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HEWLETT-PACKARD COMPANY
Intellectual Property Administration
P.O. Box 272400
Fort Collins, Colorado 80527-2400

PATENT APPLICATION

ATTORNEY DOCKET NO. 10004227-9

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Ray L. Pickup et al.

Confirmation No.: 4848

Application No.: 10/791,974

Examiner: M. Hand

Filing Date: March 3, 2004

Group Art Unit: 3761

Title: CUTANEOUS ADMINISTRATION SYSTEM

Mail Stop Appeal Brief-Patents
Commissioner For Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on April 27, 2007.

The fee for filing this Appeal Brief is (37 CFR 1.17(c)) $500.00.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

☐ (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d)) for the total number of months checked below:

☐ 1st Month $120	☐ 2nd Month $450	☐ 3rd Month $1020	☐ 4th Month $1590

☐ The extension fee has already been filed in this application.

☒ (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account 08-2025 the sum of $ 500. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 08-2025 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 08-2025 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees. A duplicate copy of this sheet is enclosed.

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Date of facsimile:
Typed Name: Christie A. Doolittle
Signature: Christie A. Doolittle

Respectfully submitted,

Ray L. Pickup et al.

By Walter W. Karnstein

Walter W. Karnstein

Attorney/Agent for Applicant(s)

Reg No. : 35,565

Date : June 27, 2007

Telephone : 503.224.6655

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: RAY L. PICKUP, CLEMENT C. LO, and WILLIAM D. NOONAN

Dated: June 27, 2007

HP Docket No. 10004227-9

Serial No. : 10/791,974

Examiner Melanie Jo Hand

Filed : March 3, 2004

Group Art Unit 3761

For : CUTANEOUS ADMINISTRATION SYSTEM

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P. O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

BRIEF OF APPELLANTS

This Brief is presented in opposition to the Examiner's rejection of claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, and 148-150 in the final Office action dated February 5, 2007 (hereinafter, "the final Office action").

I. REAL PARTY IN INTEREST

The real party in interest is Hewlett-Packard Development Company, LP, a limited partnership established under the laws of the State of Texas and having a principal place of business at 20555 State Hwy 249, Houston, Texas 77070, U.S.A. (hereinafter "HPDC"). HPDC is a Texas limited partnership and is a wholly-owned affiliate of Hewlett-Packard Company, a Delaware Corporation, headquartered in Palo Alto, CA. The general or managing partner of HPDC is HPQ Holdings, LLC.

II. RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

III. STATUS OF CLAIMS

The present application was filed with claims 1-150. The status of these claims is as follows:

Canceled – claims 1-82, 101, 110-117, 121, 122, 129, 130, 134, 135, 137-139, and 142-147.

Rejected – claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, and 148-150.

All of the rejected claims listed above are the only claims at issue in this appeal.

IV. STATUS OF AMENDMENTS

No amendments to the claims have been made subsequent to final rejection in the Office action dated February 5, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The summary is set forth in exemplary embodiments. Discussion about elements and recitation of claimed subject matter can be found at least at the locations in the specification and drawings cited below.

All of the claims at issue in this appeal are directed to a method of administering a bioactive composition to a subject. The claimed subject matter is summarized here according to the only two independent claims at issue: claim 83 and claim 91.

Independent claim 83 involves use of a jet dispenser (e.g., see pages 7-9, paragraphs [31] to [37]). A jet dispenser 200 is applied to a cutaneous surface 202 of the subject (Figure 5; page 17, paragraph [59]). The jet dispenser 200 comprises a container 208 holding the bioactive composition (Figure 5; pages 17 and 18, paragraph [60]; also see page 4, paragraph [22]). The bioactive composition is dispensed in droplets from the dispenser through at least one orifice 218 toward the cutaneous surface (Figures 5-7; page 18, paragraph [62]). The bioactive composition is retained in prolonged contact with the cutaneous surface (Figure 5; page 6, paragraphs [26] and [27]).

Independent claim 91 involves use of an inkjet dispenser (e.g., see pages 7-9, paragraphs [31] to [37]). A cutaneous patch 25 is applied to skin 24 of the subject (Figure 1; page 9, paragraph [38]). The bioactive composition is dispensed from the inkjet dispenser by ejection through an orifice to the patch (page 18, paragraph [62]; page 21, paragraph [71]; page 22, paragraph [73]).

Specific references to portions of the application are provided with the understanding that nonreferenced portions of the application also may be relevant. As such, it should be understood that the claims are not limited by the particular references made above, but rather are fully supported by the entirety of the disclosure.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants request review of the following grounds of rejection on appeal:

1. Rejection of claims 83-100, 108, 109, 118-120, 123, 126-128, 131, 140, 141, and 148-150 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No.

5,860,957 to Jacobsen et al. ("Jacobsen") in view of U.S. Patent Application Publication No. 2003/0016262 to Crivelli ("Crivelli").

2. Rejection of claims 102-107 under 35 U.S.C. § 103(a) as being unpatentable over Jacobsen, in view of Crivelli, and further in view of U.S. Patent No. 6,325,475 to Hayes et al. ("Hayes").

3. Rejection of claims 124, 125, 132, and 133 under 35 U.S.C. § 103(a) as being unpatentable over Jacobsen, in view of Crivelli, and further in view of U.S. Patent No. 5,179,947 to Meyerson et al. ("Meyerson").

4. Rejection of claim 136 under 35 U.S.C. § 103(a) as being unpatentable over Jacobsen, in view of Crivelli, and further in view of U.S. Patent No. 6,564,092 to Nakamura et al. ("Nakamura").

To summarize, appellants request review of the rejection of all pending claims under 35 U.S.C. § 103(a) over a combination of at least Jacobsen and Crivelli.

VII. ARGUMENT

The Examiner has improperly rejected each of Appellants' claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, and 148-150 under 35 U.S.C. § 103(a) as being unpatentable over at least Jacobsen and Crivelli. When the claims are reviewed under the current standards for obviousness as set by the Federal Courts and the Board of Patent Appeals and Interferences, the impropriety of the rejections becomes clear.

A. STANDARD OF REVIEW

Obviousness is a question of law based on (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). "In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). "If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

The Manual of Patent Examining Procedure sets forth three basic criteria that must be met to establish a *prima facie* case of obviousness (MPEP § 2143):

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991))

Teachings in a reference indicating that a proposed combination should not be made must be considered when determining whether there is a motivation to make the

proposed combination. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991). For example, the proposed modification cannot render the prior art unsatisfactory for its intended purpose. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). In addition, the proposed modification cannot change the principle of operation of a reference. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Furthermore, to rely on a reference as the basis for rejection of an applicant's invention, the reference must be analogous prior art, that is, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. (MPEP § 2141.01(a))

The law is "clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (citations omitted).

B. JACOBSEN AND CRIVELLI

All of the pending claims were rejected as being obvious over a combination that includes Jacobsen and Crivelli. This subsection provides a brief overview of the subject matter disclosed by each of these references.

1. The Jacobsen Patent

Jacobsen relates to a multi-pathway electronically-controlled drug delivery system that is strapped to a patient's limb or torso (e.g., as illustrated below in Figure 1 of Jacobsen).

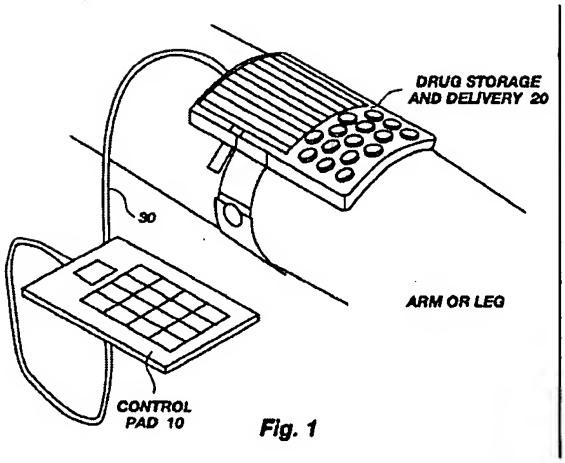

Fig. 1

The system is disclosed to administer a drug from a drug reservoir via ignition of a propellant charge that expands to force a drug from a storage reservoir to a site above or below the skin (e.g., as illustrated below in Figure 3 of Jacobsen).

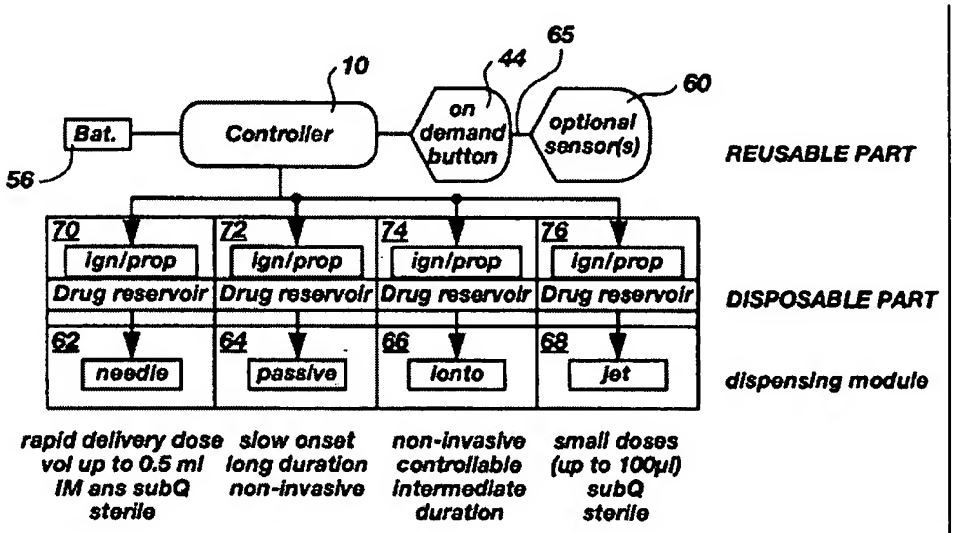

Fig. 3

The system is disclosed to administer the drug by (1) transdermal delivery via a pad on the skin (passive or iontophoretic; boxes 64 and 66 of Figure 3; e.g., see Figures 5 and 6), (2) needle-less injection through the skin via a piercing jet of fluid ("jet"; box 68 of Figure 3; e.g., see Figure 7), or (3) needle-based injection through the skin ("needle";

box 62 of Figure 3; e.g., see Figure 8). However, as described in more detail below, Jacobsen does not disclose, teach, or suggest delivery of the drug in drops of any size.

2. The Crivelli Patent

Crivelli relates to a fluid-ejection device, namely, a printhead for a thermal inkjet printer, and a method of operating the printhead. The printhead has a plurality of firing resistors (heating elements) operatively coupled to a corresponding set of orifices defined by an orifice plate. The firing resistors are energized selectively adjacent corresponding orifices such that ink is fired in droplets from the orifices. The droplets are disclosed to have a volume of 20 picoliters in an exemplary embodiment (paragraph 0026]). Crivelli discloses no other use for the fluid-ejection device other than printing with ink.

C. CLAIMS 83-90, 108, 118-120, 123, 140, 148, AND 149

1. Rejection of Claim 83

Independent claim 83 is directed to a method, as follows:

> 83. A method of administering a bioactive composition to a subject, the method comprising:
>
> applying to a cutaneous surface of the subject a jet dispenser comprising a container holding the bioactive composition;
>
> dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface; and
>
> retaining the bioactive composition in prolonged contact with the cutaneous surface.

In the final Office action (dated February 5, 2007), the Examiner rejected claim 83 over a combination of Jacobsen and Crivelli. However, Appellants submit that the Examiner

has not established a *prima facie* case of obviousness. In particular, Appellants submit that (a) the cited references, alone or in combination, do not teach or suggest every element of claim 83, and (b) there is no teaching, suggestion, or motivation to combine the references.

2. *Jacobsen and Crivelli Do Not Teach or Suggest Every Element of Claim 83*

Appellants submit that neither Jacobsen nor Crivelli discloses, teaches, or suggests "dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface" or "retaining the bioactive composition in prolonged contact with the cutaneous surface," as recited by claim 83. However, in the final Office action, the Examiner asserted that Jacobsen teaches all elements of claim 83, including dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface and retaining the bioactive composition in prolonged contact with the cutaneous surface (page 4, last five lines, to page 5, first two lines). Appellants strongly disagree as detailed below.

Based on the Examiner's assertion that Jacobsen teaches all elements of claim 83, Appellants question the Examiner's purpose for including Crivelli in the rejection. In the final Office action, the Examiner explained the role of Crivelli in the rejections as follows: "the prior art of Crivelli was introduced to remedy the deficiency of Jacobsen with respect to droplet volume" (page 3, lines 6 and 7). However, pending claim 83 does not recite a droplet volume. In any case, appellants submit that the rejections are based on the Examiner's misinterpretation of Jacobsen, whatever the role of Crivelli in the rejections.

Jacobsen does not disclose, teach, or suggest dispensing a bioactive composition in drops (or droplets) of any size. To support this position, Appellants previously explained that the passive and iontophoretic delivery mechanisms disclosed in Figures 5 and 6, and the needle-based delivery mechanism of Figure 8, do not involve formation of drops or droplets of any size (Amendment dated November 13, 2006). The previous explanation regarding Figure 5 is repeated here with minor modifications.

Figure 5 of Jacobsen, which is reproduced here to facilitate review, relates to transdermal delivery via a pad. The device 200 of Figure 5 has a pod housing 250 divided into an upper chamber 290 and a lower chamber 300 by a piston 320. Ignition of a propellant charge 280 located in the upper chamber forces the piston toward an aperture 350 formed in the pod housing. Aperture 350 provides an outlet for a fluid drug disposed in lower chamber 300. Pressure exerted on the drug in the lower chamber breaks a foil barrier 360 covering aperture 350 such that "the drug flows out of the chamber 300 and, in this particular drug delivery system, fills a pad 370 directly beneath the pod aperture 350" (col. 10, lines 31-33; emphasis added). Furthermore, Jacobsen discloses that "the drug is constrained by the surrounding pad 370, and is absorbed through the patient's skin" (col. 10, lines 33-35).

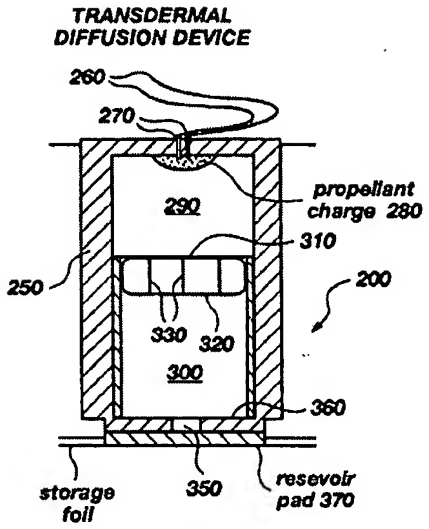

Fig. 5

However, device 200 does not dispense the drug in drops of any size, and thus particularly does not involve "dispensing the bioactive composition in droplets," as recited by claim 83. In particular, device 200 of Jacobsen blocks drop formation because Jacobsen discloses placement of pad 370 in abutment with aperture 350 such that drops cannot form as the fluid drug flows from the aperture.

In response, in the final Office action the Examiner "restated the rejection to refer primarily to Figure 7 for clarity" (page 2, last line). As described in the following paragraphs, use of the device of Figure 7 involves neither (a) "dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface" nor (b) "retaining the bioactive composition in prolonged contact with the cutaneous surface," as recited by claim 83.

Figure 7 of Jacobsen, which is reproduced here to facilitate review, relates to a jet delivery device 450 for drug delivery. Device 450 is disclosed to be similar in structure to the transdermal delivery device 200 of Figure 5 and thus the description of

device 450 that follows relies in part on Jacobsen's discussion of device 200. Device 450 has a pod housing divided into an upper chamber and a lower chamber 300 by a piston 320.

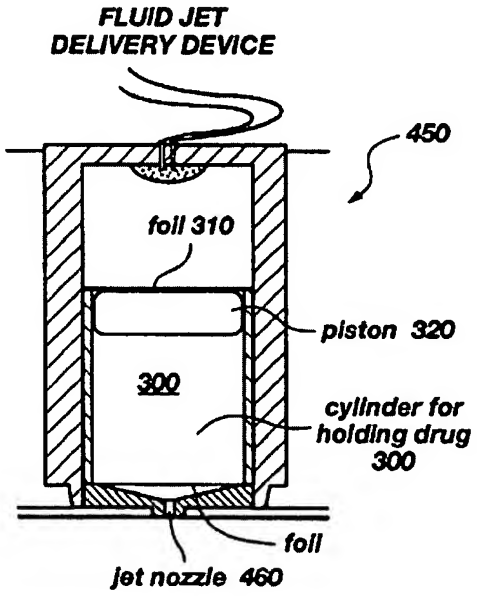

Fig. 7

Ignition of a propellant charge located in the upper chamber forces the piston toward an aperture or jet nozzle 460 formed in the pod housing. Aperture 460 provides an outlet for a fluid drug disposed in lower chamber 300. Pressure exerted on the drug in the lower chamber breaks a foil barrier ("foil") separating the drug in cylinder 300 from aperture 460 (and thus keeping the drug out of contact with skin before propellant ignition). Aperture 460 "is in direct contact with the patient's skin" because "[c]ontact is necessary to facilitate the delivery of drug directly into the patient's tissue" (col. 11, lines 13-15; emphasis added by Appellants). Furthermore, Jacobsen states that "[b]y creating a sufficiently large pressure and using a small nozzle, the drug is inserted into subcutaneous skin layers without a needle, as will be understood by those skilled in the

art" (col. 11, lines 20-23). Appellants submit that those skilled in the art will recognize this method of drug delivery as needle-free injection, which is classified by the United States Patent and Trademark Office in, for example, Class 604, Subclass 68 or 69.

Jacobsen thus discloses a needle-free injection mechanism in Figure 7 in which a high-pressure stream (not drops) of fluid drug from device 450 pierces the skin. In addition, since aperture 460 is disclosed to be in contact with skin, this contact, as in device 200 of Figure 5, would prevent formation of drops as the fluid drug leaves nozzle 460, at any pressure of delivery of the fluid from device 450. Furthermore, delivery of the fluid drug of device 450 does not involve "retaining the bioactive composition in prolonged contact with the cutaneous surface," as recited by claim 83. In particular, the fluid drug is kept out of contact with the cutaneous surface by a foil barrier before delivery and then is delivered very rapidly below the cutaneous surface by the sufficiently large pressure and small nozzle disclosed by Jacobsen.

Appellants submit that the Examiner has adopted an erroneous interpretation of Jacobsen in rejecting the claims. For example, the Examiner stated the following in disagreeing with Appellants in the final Office action (page 2):

> Jacobsen explicitly teaches a drug delivery apparatus that is held on a patient's skin surface for single or multiple dosages and is intended for use by patients who lack the skill or time or who are physically challenged. (Col. 4, lines 49-61) Thus the device is intended for wear over a prolonged time period on the skin surface and thus retains the drug dispenser and drug held therein in prolonged contact with the cutaneous surface. [emphasis added by Appellants]

Applicants strongly disagree with the last sentence. Each drug held in a drug dispenser of Jacobsen is held out of contact with the cutaneous surface. In particular, prior to delivery, each drug is separated from the cutaneous surface by a barrier (e.g., foil

barrier 360 of Figure 5, the lower "foil" of Figure 7, or seal 540 of Figure 8). As another example of misinterpretation of Jacobsen, in modifying the rejection in the final Office action, the Examiner stated that Figure 7 of Jacobsen shows "a fluid jet drug delivery device in which the drug is administered using a propellant through a nozzle, which is clearly not a single event dosage using a stream." Appellants disagree strongly with the Examiner's position about the device of Figure 7, maintaining their assertion that Figure 7 shows a device that produces a stream of drug for a single dosage. In particular, Appellants contend that expelling all of the drug from the drug reservoir of device 450 as a single stream in a single dosage is necessary to insert the drug efficiently "into subcutaneous skin layers without a needle" (Jacobsen, col. 11, line 22). In addition, Appellants contend that delivery of the drug in Jacobsen proceeds uncontrollably and to completion after ignition of the propellant.

It is submitted that the combination of Jacobsen and Crivelli does not produce the claimed invention. In particular, Jacobsen discloses the placement of a drug-receiving pad in abutment with an aperture of a drug delivery device (e.g., see Figure 5 above), for cutaneous delivery of the drug. (Crivelli does not teach or suggest any type of cutaneous delivery or use of a drug for any purpose.) Accordingly, even if it would have been obvious to combine these references, and Appellants contend that it would not have been, the combination of Jacobsen and Crivelli would place the drug-receiving pad of Jacobsen in abutment with the orifice plate of the printhead of Crivelli. In this configuration, the pad would block droplet formation by the printhead and would tend to draw ink from the printhead by capillary action, thereby rendering the printhead non-

functional for its intended purpose, namely, dispensing droplets. Furthermore, it would not have been obvious to space the pad from the printhead of Crivelli because this would have been expected to permit evaporation of fluid from the pad, thereby drying out the pad and preventing the drug from diffusing through the skin.

3. *Not Obvious to Combine Jacobsen and Crivelli*

Even if the combination of Jacobsen and Crivelli would have produced the claimed invention, and Appellants contend that it would not, Appellants submit that it would not have been obvious to combine these two references. As described above, Jacobsen relates to delivery of a jet of fluid (a drug) as an uninterrupted stream, not in drops, in response to a single firing event. In contrast, Crivelli relates to thermal inkjet printing, which involves patterned delivery of a large number of ink droplets to print media, for rapid evaporation, based on a corresponding large number of firing events. Accordingly, Jacobsen and Crivelli relate to completely different approaches to, and reasons for, delivering fluid. Furthermore, at the time of the invention, a method resulting from combination of these references would have been considered by the ordinarily skilled artisan to be inefficient and complicated for drug delivery. For example, Jacobsen discloses an exemplary drug volume of 0.1 mL (100,000,000 picoliters) for the device of Figure 7 (col. 10, lines 48-50), to be delivered as a single dose by a transdermal drug delivery system, in response to a single actuation event (propellant ignition). Crivelli's printhead, based on a disclosed volume per droplet of 20 picoliters, would require five million droplets and thus five million actuation events to deliver 0.1 mL of drug. Accordingly, Appellants submit that there is no teaching, suggestion, or

motivation to modify a drug delivery system (Jacobsen) that delivers a drug dose as a single, non-patterned fluid stream, in response to a single actuation event, with a printhead (Crivelli), which would deliver a corresponding volume of ink as millions of droplets in response to millions of actuation events.

4. Allowability of the Claims

In summary, Appellants submit that independent claim 83 is patentable over the cited references. Claim 83 thus should be allowed. Claims 84-90, 108, 118-120, 123, 140, 148, and 149, which depend ultimately from claim 83, also should be allowed for at least the same reasons as claim 83.

D. CLAIMS 91-100, 109, 126-128, 131, 141, AND 150

Independent claim 91 is directed to a method, as follows:

> 91. (Previously Presented) A method of administering a bioactive composition to a subject, the method comprising:
>
> applying a cutaneous patch to skin of the subject; and
>
> dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice to the patch.

In the Office action, the Examiner rejected claim 91 over a combination of Jacobsen and Crivelli. However, as described above in relation to claim 83, Appellants submit that it would not have been obvious to combine Jacobsen with Crivelli because Jacobsen does not disclose a delivery mechanism that produces drops of any size, because this combination disrupts the ability of the inkjet dispenser to produce droplets, and because the references involve very different approaches to and reasons for delivering fluid.

For at least these reasons, claim 91 should be allowed. Claims 92-100, 109, 126-128, 131, 141, and 150, which depend ultimately from claim 91, also should be allowed for at least the same reasons as claim 91.

E. CLAIMS 102-107

Claims 102-107 were rejected over a combination of Jacobsen, Crivelli, and Hayes. Each of these claims depends from independent claim 83 or independent claim 91. The added reference, Hayes, does not cure any of the defects described above for the rejection of parent claims 83 and 91 over Jacobsen and Crivelli, and thus claims 102-107 are patentable for at least the same reasons as claim 83 and claim 91. In addition, each of these claims is patentable because it would not have been obvious to combine Crivelli and Hayes. Crivelli relates to a fluid-ejection device and method that is intended to reduce aerosol generation (paragraph [0005]). In contrast, Hayes relates to a device for presenting airborne materials to the nose, that is, a device for creating aerosols (for inhalation or sniffing). Accordingly, it would not have been obvious to combine Crivelli and Hayes because these references have contradictory goals. Claims 102-107 thus also should be allowed for at least this additional reason.

F. CLAIMS 124, 125, 132, AND 133

Claims 124, 125, 132, and 133 were rejected over a combination of Jacobsen, Crivelli, and Meyerson. Each of these claims depends from independent claim 83 or independent claim 91. The added reference, Meyerson, does not cure any of the defects described above for the rejection of parent claims 83 and 91 over Jacobsen and

Crivelli, and thus claims 124, 125, 132, and 133 are patentable for at least the same reasons as claim 83 and claim 91.

G. CLAIM 136

Claim 136 was rejected over a combination of Jacobsen, Crivelli, and Nakamura. Claim depends from independent claim 83. The added reference, Nakamura, does not cure any of the defects described above for the rejection of parent claim 83 over Jacobsen and Crivelli, and thus claim 136 is patentable for at least the same reasons as claim 83.

H. CONCLUSION

For at least the reasons stated above, Appellants assert that there is no *prima facie* case of obviousness for rejection of the pending claims. Accordingly, Appellants submit that the rejection of claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, and 148-150 under 35 U.S.C. § 103(a) is improper and should be reversed.

VIII. CLAIMS APPENDIX

83. A method of administering a bioactive composition to a subject, the method comprising:

applying to a cutaneous surface of the subject a jet dispenser comprising a container holding the bioactive composition;

dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface; and

retaining the bioactive composition in prolonged contact with the cutaneous surface.

84. A method according to claim 83, wherein retaining the bioactive composition in prolonged contact with the cutaneous surface comprises dispensing the bioactive composition on to a dermal patch that is retained on the cutaneous surface.

85. A method according to claim 84, wherein the dermal patch is an adhesive dermal patch that is applied to the cutaneous surface prior to dispensing the bioactive composition from the dispenser.

86. A method according to claim 85, wherein the dermal patch comprises a selectively removable cover that is removed prior to dispensing the bioactive composition into the patch, and is subsequently replaced on the patch to improve retention of the bioactive composition in the patch.

87. A method according to claim 83, wherein retaining the bioactive composition in prolonged contact with the cutaneous surface comprises providing a seal between the dispenser and cutaneous surface, to form a substantially sealed chamber between the dispenser and the cutaneous surface, and retaining the dispenser in prolonged contact with the seal.

88. A method according to claim 83, further comprising repeatedly dispensing the bioactive composition toward the cutaneous surface.

89. A method according to 88, further comprising resupplying the dispenser with the bioactive substance.

90. A method according to claim 89, wherein resupplying the dispenser comprises replacing a container in the dispenser.

91. A method of administering a bioactive composition to a subject, the method comprising:

applying a cutaneous patch to skin of the subject; and

dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice to the patch.

92. A method according to claim 91, further comprising dispensing the bioactive composition to the patch at intervals to provide sustained dosages of the bioactive composition from the patch to the subject.

93. A method according to claim 92, wherein the intervals are preselected intervals.

94. A method according to claim 91 further comprising dispensing the bioactive composition from the dispenser to the patch when an amount of the bioactive composition in the patch falls below a desired level.

95. A method according to claim 91:

wherein said dispensing further comprises dispensing a second substance from the dispenser to the patch; and

the method further comprises mixing the bioactive composition with dispensing.

96. A method according to claim 95 wherein said mixing occurs between said orifice and said patch.

97. A method according to claim 95 wherein said mixing occurs within said patch.

98. A method according to 91 further comprising containing said bioactive composition with a container portion of said inkjet dispenser prior to said dispensing.

99. A method according to claim 98 further comprising refilling said container portion with said bioactive composition.

100. A method according to claim 99 further comprising removing said container portion from the inkjet dispenser prior to said refilling, and after said refilling, replacing said container portion for further dispensing.

102. A method according to claim 83, wherein said dispensing comprises using a thermal droplet jet dispenser.

103. A method according to claim 83, wherein said dispensing comprises using a piezoelectric droplet jet dispenser.

104. A method according to claim 83, wherein said dispensing comprises using a silicon electrostatic actuated droplet jet dispenser.

105. A method according to claim 91, wherein said inkjet dispenser used in said dispensing comprises a thermal inkjet dispenser,

wherein dispensing the bioactive composition from the thermal inkjet dispenser comprises

receiving the bioactive composition into a feed chamber from a reservoir in the dispenser;

flowing the bioactive composition from the feed chamber into a vaporization chamber in the dispenser;

energizing a firing resistor in the vaporization chamber; and

ejecting the bioactive composition as a droplet from the vaporization chamber.

106. A method according to claim 91, wherein said inkjet dispenser used in said dispensing comprises a piezoelectric inkjet dispenser,

wherein dispensing the bioactive composition from the piezoelectric inkjet dispenser comprises

receiving the bioactive composition into a piezoelectric chamber from a storage chamber in the dispenser;

passing an electric current through a piezoelectric member in the chamber, thereby expanding the piezoelectric member; and

expelling the bioactive composition as a droplet from the vaporization chamber.

107. A method according to claim 91, wherein said inkjet dispenser used in said dispensing comprises a silicon electrostatic actuated inkjet dispenser.

108. A method according to claim 83, further comprising:

optically reading subject identification information with an optical reading device of said jet dispenser;

correlating said subject identification information with prescribed dosage information; and

wherein said dispensing comprises dispensing the bioactive composition according to said prescribed dosage information.

109. A method according to claim 91, further comprising:

optically reading subject identification information with an optical reading device of said inkjet dispenser;

correlating said subject identification information with prescribed dosage information; and

wherein said dispensing comprises dispensing the bioactive composition according to said prescribed dosage information.

118. A method according to claim 83, further comprising:

monitoring a physical parameter of the subject; and

in response to said monitoring, adjusting said dispensing.

119. A method according to claim 118, wherein said physical parameter comprises heartbeats.

120. A method according to claim 118, wherein said physical parameter comprises breathing.

123. A method according to claim 118, wherein said monitoring comprises using a monitor portion of the jet dispenser.

124. A method according to claim 123, wherein said monitor portion comprises a mechanical sensor.

125. A method according to claim 124, wherein said mechanical sensor comprises an accelerometer.

126. A method according to claim 91, further comprising:

monitoring a physical parameter of the subject; and

in response to said monitoring, adjusting said dispensing.

127. A method according to claim 126, wherein said physical parameter comprises heartbeats.

128. A method according to claim 126, wherein said physical parameter comprises breathing.

131. A method according to claim 126, wherein said monitoring comprises using a monitor portion of the jet dispenser.

132. A method according to claim 131, wherein said monitor portion comprises a mechanical sensor.

133. A method according to claim 132, wherein said mechanical sensor comprises an accelerometer.

136. A method according to claim 83, further comprising:

applying a bioactive composition attracting agent to a treatment location on the cutaneous surface of the subject;

pulling the bioactive composition toward said agent; and

penetrating said agent with the bioactive composition to treat the treatment location with the bioactive composition.

140. A method according to claim 83, further comprising manually triggering an activation device after said applying and before said dispensing, with said dispensing occurring in response to said triggering.

141. A method according to claim 91, further comprising manually triggering an activation device after said applying and before said dispensing, with said dispensing occurring in response to said triggering.

148. A method according to claim 83, further comprising:

storing the bioactive composition in a collapsible bladder; and

conveying the bioactive composition from the collapsible bladder to the jet dispenser.

149. A method according to claim 148 wherein said conveying comprises conveying the bioactive composition through tubing.

150. A method according to claim 91, further comprising:

storing the bioactive composition in a collapsible bladder; and

conveying the bioactive composition from the collapsible bladder to the inkjet dispenser through tubing.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

Respectfully submitted,

KOLISCH HARTWELL, P.C.

Walter W. Karnstein
Registration No. 35,565
520 S.W. Yamhill Street, Suite 200
Portland, Oregon 97204
Telephone: (503) 224-6655
Facsimile: (503) 295-6679
Attorney for Appellants

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Christie A. Doolittle